

Applicants: Pablo Rubinstein et al.
Serial No.: 09/855,789
Filed: May 15, 2001
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REMARKS

Claims 25 and 27-32 were pending in the subject application. By this Amendment, applicants have amended claim 25 and added new claims 33-73 to better clarify applicants' invention. Accordingly, upon entry of this Amendment, claims 25 and 27-73 will be pending and under examination.

Applicants maintain that the amendments to the claims do not raise an issue of new matter. Support for the amendments to claim 25 can be found *inter alia* in the specification as originally filed at least on page 22, last two sentences of the first paragraph, and in original claims 18 and 22. Support for new claims 33 and 48 can be found *inter alia* in the specification as originally filed at least on page 10, 2nd to last paragraph; page 14, lines 10-11; and page 22, 1st paragraph. Support for new claims 34 and 49 can be found *inter alia* in the specification as originally filed at least on page 10, 2nd to last paragraph, and page 22, 1st paragraph, and in original claim 22. Support for new claims 35 and 36 can be found *inter alia* in the specification as originally filed at least in the sentence bridging pages 12 and 13. Support for new claims 39, 52, 62, and 71 can be found *inter alia* in the specification as originally filed at least on page 22, 1st paragraph. Support for new claims 40, 53, 63, and 72 can be found *inter alia* in the specification as originally filed at least on page 20, last paragraph through page 21, last paragraph, and in original claim 21. Support for new claim 54 can be found in claim 25 and *inter alia* in the specification as originally filed at least on page 10, 2nd to last paragraph; page 14, lines 10-11; and page 22, 1st paragraph. Support for new claim 64 can be found in claim 25 and *inter alia* in the specification as originally filed at least on page 10, 2nd to last paragraph. Support for the other claim amendments can be found at least in the previous version of the claims. Accordingly, applicants respectfully request that the amendments be entered.

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Rejections under 35 U.S.C. §112, second paragraph

Claims 25 and 27-32 are rejected under 35 U.S.C. §112, second paragraph. The Examiner stated that the claim language "less than all of plasma and red blood cells" is indefinite.

In order to better clarify the subject invention, applicants have herein above amended claim 25 to recite "less than all of plasma contained in said cord blood or placental blood, less than all of red blood cells contained in said cord blood or placental blood..." Applicants maintain that the phrase "less than all of" is to be understood in the context of the ordinary, English-language meaning of the phrase. As an example, if the cord or placental blood contained 100 red blood cells, then the therapeutic product of Claim 25 would contain less than 100 red blood cells.

Applicants maintain that the skilled artisan would readily understand the subject matter that applicants regard as the invention. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

Rejections under 35 U.S.C. §102

Claims 25 and 27 are rejected under 35 U.S.C. §102(a) as anticipated by Rubinstein et al. (May, 1993).

Applicants respectfully traverse this rejection. Rubinstein et al. (1993) disclose whole placental blood that is not subjected to fractionation. In contrast, the claimed therapeutic product contains less than all of the plasma contained in cord blood or placental blood and less than all of the red blood cells contained in cord blood or placental blood. Accordingly, Rubinstein et al. (1993) do not anticipate the claimed invention.

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Claims 25, 27 and 28 are rejected under 35 U.S.C. §102(b) as anticipated by Boyse et al. (U.S. Patent No. 5,004,681).

Applicants respectfully traverse this rejection. The claimed invention is a therapeutic product that "is characterized by a white cell viability greater than 80% with respect to said cord blood or placental blood." In contrast, Boyse et al. do not achieve comparable white cell viability. Boyse et al. report maximum recovery rates of only about 33% - 64% for hematopoietic progenitor cells for white blood cells following various cell separation procedures (see Table IV, column 40, Experiments 1 and 2, CFU-GM and CFU-GEMM cell types). For example, in Experiment 1 as reported in Table IV, for CFU-GM day 7 cells, whole blood contains 167×10^3 progenitor cells whereas whole blood to which NH_4Cl has been added to lyse mature erythrocytes contains only 55×10^3 progenitor cells. Thus, the recovery rate of CFU-GM day 7 progenitor cells following this separation procedure is $55/167$ or about 33%. Accordingly, Boyse et al. do not anticipate the claimed invention.

Applicants maintain that neither Rubinstein et al. nor Boyse et al. anticipate the claimed subject invention and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 30-32 under 35 U.S.C. §103(a) as obvious over Boyse et al. (U.S. Patent No. 5,004,681).

In view of the amendments made hereinabove to claim 25, and in view of the preceding remarks, applicants maintain that Boyse et al. do not render obvious claims 30-32 which depend from, and further limit, claim 25. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

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Allowable Subject Matter

The Examiner indicated that Claim 29 would be allowable if rewritten to overcome the rejection under 35 U.S.C. §112, second paragraph, set forth above and to include all of the limitations of the base claim and any intervening claims. Applicants thank the Examiner for this indication of allowable subject matter. However, in view of the amendments and remarks made hereinabove, applicants request that the Examiner reconsider the allowability of all of the pending claims.

Associate Power of Attorney

As requested by Examiner Bianco during a telephone call with the undersigned attorney, attached hereto is an Associate Power of Attorney for the undersigned attorney.

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Conclusions

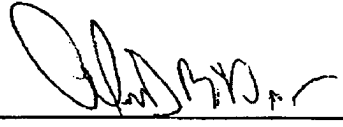
In light of the amendments and the remarks made hereinabove, applicants respectfully request withdrawal of the rejections set forth in the July 15, 2003 Office Action and passage of all of the pending claims to allowance. If there are any minor matters that would prevent allowance of the claims, applicants request that the Examiner contact the undersigned attorney.

A check for \$700.00 is enclosed to cover the \$110.00 fee for a one month extension of time, the \$504.00 fee for 28 claims in excess of 20 claims (\$18.00 per each excess claim) and the \$86.00 fee for one independent claim in excess of 3 independent claims. No additional fees are deemed necessary in connection with the filing of this Amendment. However, if there are unanticipated fees required to maintain the pendency of this application, the PTO is authorized to withdraw the amount of any such fee from Deposit Account 01-1785. Overcharges may also be credited to Deposit Account 01-1785.

Respectfully submitted,

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